August 29, 2019

Apollo Endosurgery
David Hooper
Director of Regulatory Affairs
1120 S. Capital of Texas Hwy
Austin, Texas 78746

Re: K191439
Trade/Device Name: OverStitch Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCW
Dated: May 29, 2019
Received: May 30, 2019

Dear David Hooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Dr. Nina Mezu-Nwaba
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191439

Device Name
OverStitch Endoscopic Suturing System

Indications for Use *(Describe)*
The OverStitch Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Owner's Name & Address:	Apollo Endosurgery 1120 S. Capital of Texas Hwy. Building 1, Suite 300 Austin, TX 78746
Contact Person:	David Hooper Director, Regulatory Affairs Phone: (512)-618-4855 Email : David.Hooper@apolloendo.com
Date:	August 29, 2019
510(k) Number:	K191439
Trade Name:	OverStitch™ Endoscopic Suturing System
Common Name:	Endoscopic Tissue Approximation Device
Product Code:	OCW
Classification:	Class II (21 CFR 876.1500)
Classification Name	Endoscope and Accessories
Predicate Devices:	K181141 – OverStitch™ Endoscopic Suturing System
Device Description	The OverStitch™ Endoscopic Suturing System and accessories are intended for endoscopic placement of sutures and approximation of soft tissue within the gastrointestinal tract utilizing either a dual channel or single-channel endoscope. The system is comprised of the Needle Driver Assembly and Anchor Exchange Device (collectively referred to as ESS), and accessories such as the Tissue Helix, Suture Cinch and Suture-Anchor Assembly devices. All devices are sterile packaged and designed for single use and are manufactured from various thermoplastic, silicone, stainless steel and other medical grade materials. OverStitch ESS The OverStitch ESS is designed for compatibility with dual channel endoscopes. The endcap of the Needle Driver Assembly attaches to the distal end of the endoscope, and the handle attaches to the proximal end. The handle of the Needle Driver Assembly is squeezed to actuate the needle body and exchange the Suture-Anchor Assembly with the Anchor Exchange to perform stitching operations.

OverStitch Sx ESS

The OverStitch Sx ESS is designed for compatibility with single channel endoscopes. The ESS is mounted onto the endoscope using silicone straps distributed along the length of the catheter and endcap assembly. The external catheter sheath has two working channels through which the Anchor Exchange and OverStitch accessories can operate, independent of the endoscope channel. The handle of the Needle Driver Assembly is squeezed to actuate the needle body and exchange the proprietary Suture-Anchor Assembly with the Anchor Exchange to perform stitching operations.

OverStitch Tissue Helix

The OverStitch Helix is an optional device that is designed to acquire tissue by rotating the device handle into targeted area until tissue is gathered into the exposed helix coil. The acquired tissue is then pulled into proximity of the needle body to complete the stitching operation.

OverStitch Suture-Anchor Assembly

The OverStitch Suture-Anchor Assembly is comprised of a 510(k) cleared suture product, manufactured from either polydioxanone or polypropylene materials attached to an implantable anchor manufactured from cobalt chrome and stainless steel. The Anchor component is intended to function with the OverStitch ESS devices to perform stitching operations and serves as an anchor to secure suture placement.

OverStitch Suture Cinch

The Overstitch Suture Cinch device is comprised of thermoplastic and stainless steel materials and includes an implantable PEEK Cinch component designed to secure the placement of suture as a final step of an OverStitch procedure. The device functions by squeezing the handle and deploying the PEEK components that press-fit onto the tail end of the suture to maintain suture position in situ.

Indications for Use:

The OverStitch Endoscopic Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue.

Modifications:

The OverStitch Endoscopic Suturing System has been modified to add a new product code option for the OverStitch 2-0 Polypropylene Suture-Anchor Assembly. The remaining components of the system remain unchanged.

Technological Characteristics:

SUTURE-ANCHOR ASSEMBLY	**OverStitch 2-0 Polypropylene Suture**
Single Use	Yes
Shelf-Life Claim	1-year
Materials-Anchor	• Stainless Steel 316L • Cobalt Chromium MP35
Materials-Suture	• USP 2-0 Polypropylene Chemical Formula: -(CH(CH3)-CH2)n • Copper Phthalocyanine Blue (Below 0.5 WT %) in accordance with 21CFR 74, 3045
Dimensions	Anchor Length: 6.6 mm O.D.: 1.0 mm Suture Length: 185 cm O.D.: 2.0 mm
Suture Anchor Design	Suture-Anchor has a recessed feature on one end designed to engage with the Anchor Exchange, and a latch feature on the opposite end designed to engage with the Needle Body Assembly. The suture is swaged onto the center of the needle body to allow for the needle body to double as an anchor for the suture construct
Sterilization	Terminally sterilized to SAL 10^{-6} using a validated EO method

Non-Clinical Performance Data: Appropriate product testing was performed to evaluate conformance to USP requirements, product specifications, and equivalence to the predicate design. The device was evaluated against individual functional and reliability requirements, as well as OverStitch Endoscopic Suturing System compatibility.

Performance Testing

Bench testing included needle passing reliability, Suture Cinch deployment and pull-off strength, tensile strength per USP <881>, needle pull off strength per USP <871> and suture diameter measuremnts per USP <861>.

Packaging Integrity

Packaging Integrity was confirmed by repeating testing in accordance with ASTM F1929-15, ASTM DI69-16 and ASTM F1886/F1886M-16.

The results of all studies confirmed substantial equivalence between the subject and predicate designs, and that no new issues of safety or efficacy were raised.

Biocompatibility: Biocompatibility assessments were performed in accordance with the appropriate risk category requirements, as defined in ISO 10933-1. Testing included extractable and leachable studies in

	accordance with ISO 10993-18: 2005 and a toxicological risk assessment in accordance with ISO 10993-17: 2002
Clinical Performance Data:	Clinical testing was not required to demonstrate substantial equivalence.
Basis of Substantial Equivalence:	Based on a comparison of indications for use and technological characteristics, the proposed devices have demonstrated substantial equivalence to their predicate device.